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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,116	07/19/2005	Jean-Francois Zagury	ZAGURY9	7529

1444 7590 11/02/2007  
BROWDY AND NEIMARK, P.L.L.C.  
624 NINTH STREET, NW  
SUITE 300  
WASHINGTON, DC 20001-5303

EXAMINER
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MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

MAIL DATE	DELIVERY MODE
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11/02/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/510,116

Applicant(s)

ZAGURY, JEAN-FRANCOIS

Examiner

Prema M. Mertz

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 15-27 is/are pending in the application.
- 4a) Of the above claim(s) 15-19 and 24-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 20-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. Claims 2-13 have been canceled (5/31/07). Claim 14 has been canceled (10/15/07).

Withdrawn amended claims 15-19, 24-25, previously amended claims 1 and 20-23 (10/15/07) and new claims 26-27 are pending in the instant application.

Amended claims 1, 20-23 (10/15/2007) are under consideration by the Examiner.

2. Receipt of applicant's arguments filed on 10/15/2007 is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 10/15/2007:

(i) the rejection of claims 1, 14, 20-23, under 35 U.S.C. 112, second paragraph; Applicant's arguments with respect to these claims have been considered but are moot in view of the new ground(s) of rejection.

(ii) the rejection of claims 1, 14, 22 under 35 U.S.C. 102(a) as being anticipated by U.S. Patent No. 6,440,694 ('694 patent).

(iii) the rejection of claims 1, 14, 22 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,440,694 ('694 patent).

4. Applicants arguments filed on 10/15/2007 have been fully considered but were persuasive in part. The new issues are stated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 U.S.C. § 112 second paragraph***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 20-23, are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 4, is vague and indefinite because it recites "originating from a human cytokine". It is unclear whether the excipient or the peptide originates from a human cytokine

Claims 20-23, are rejected as vague and indefinite insofar as they depend on rejected claim 1 for their limitations.

***Claim rejections-35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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6a. Claims 1, 22, are rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Patent No. 5,158,934 ('934 patent).

The reference teaches an amino acid region of TNF- $\alpha$  which is 100% identical to the peptide of amino acid sequence set forth in SEQ ID NO:7 contained in an amino acid fragment 24 amino acids in length. The reference, column 6, lines 21-30 recites that there is an interesting region of homology between coding region of clone 78258 i.e. SEQ ID NO:5 of the reference compared to SEQ ID NO:6 of a region of TNF- $\alpha$ . A comparison of the claimed peptide of SEQ ID NO:7 and the peptide (SEQ ID NO:5 of the reference is set forth below and indicates that the amino acid sequence disclosed in the reference is 100 % identical to that of SEQ ID NO:7 presented in the instant application.

Query Match 100.0%; Score 74; DB 2; Length 24;  
Best Local Similarity 100.0%; Pred. No. 1.5e-06;  
Matches 15; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 FQLEKGDRLSAEINR 15  
          |||||||  
Db 10 FQLEKGDRLSAEINR 24

However, the '934 patent never produced the peptide fragment as a pharmaceutical composition in a suitable pharmaceutical excipient. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the instant invention was made to place the peptide of SEQ ID NO:5 of the reference, in a pharmaceutically acceptable excipient, to determine the characteristics and function of the peptide. To have produced a composition comprising the peptide of SEQ ID NO:5 in a pharmaceutically acceptable excipient by employing those methods that were old and well known in the art of protein purification at the time that the instant

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invention was made would have been *prima facie* obvious to an artisan in light of the '934 patent because the '934 patent teaches that this region is interesting. Furthermore, it would have been obvious to one of ordinary skill in the art at the time that the invention was made, to merely admix a carrier with a peptide, and obtaining such does not render the resulting composition patentable if it would have been obvious to formulate the peptide with a pharmaceutically acceptable carrier relative to its art intended use (In re Rosicky 125 USPQ 341).

### ***Conclusion***

No claim is allowable.

Claims 1, 20-23 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Advisory Information***

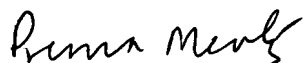
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Prema Mertz Ph.D., J.D.

Primary Examiner

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October 29, 2007